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Italian Medicines Agency  
GCP Promotion Unit, GCP and  
Pharmacovigilance Inspectorate

## INTERNATIONAL ROUND TABLE

### ***“Biomedical Research in Developing Countries: The Promotion of Ethics, Human Rights and Justice”***

15-16 DECEMBER 2008

FAO, Iran Room, V.le delle Terme di Caracalla, Rome

#### Programme

#### ***Monday, 15 December***

h. 8.00      ***Registration of Participants***

h. 9.00      Welcome Messages by the Representative of the Italian Ministry of Foreign Affairs, Minister Mario Sammartino, Deputy Director of Directorate General for Development Cooperation and by the President of the National Health Institute of Italy, Professor Enrico Garaci

Welcome

Presentation of the Round Table, Sandro Calvani, Director, UNICRI

Introduction to the Meeting, Guido Rasi, Chief Executive, Italian Medicines Agency, AIFA

h. 9.30      ***I Session: The International Legislation and Guidelines Protecting the Research Participants***

Chairpersons: Jan Helge Solbakk, Charles Mgone

Henk ten Have, Director, Division of Ethics of Sciences and Technology, UNESCO: *“The Universal Declaration on Bioethics and Human Rights and the UNESCO work in building capacity for ethical review”*

Eva Bagenholm, Chair, WMA Committee on Medical Ethics, President of the Swedish Medical Association, and Julia Seyer, WMA Medical Ethics: *“WMA Declaration of Helsinki, Ethical Principles for Medical Research Involving Humans Subjects”*

Maurizio Salvi, European Commission, European Group on Ethics in Science and New Technologies – EGE, Head of Secretariat, Policy Adviser at the Bureau of European Policy Advisers to the President of the European Commission: *“The role and functions of the European Commission in protecting human participants in biomedical research”*

Marie-Charlotte Bouesséau, Team Leader, Ethics and Health, Department of Ethics, Equity, Trade and Human Rights, WHO Geneva: *“The WHO activities: strengthening ethics review of research involving human participants”*

- h. 10.30 Discussion
- h. 11.00 **Focus on Africa: National and Regional Initiatives on Ethics in Biomedical Research**
- Chairpersons: Umberto Filibeck, Alessandra O'Neil
- Wenceslaus L. Kilama, Managing Trustee, Tanzania Commission for Science and Technology: *"AMANET activities in strengthening ethical review capacity across Africa"*
- Chris Zielinski, Technical Coordinator, Research for Health, WHO/AFRO: *"Status of ethical review of biomedical research in the WHO African Region"*
- h. 11.30 Coffee Break
- h. 12.00 Alice Paola Brizi, Researcher, Justice Protection and Ethics Unit, UNICRI: *"The state of legislation regarding ethics in biomedicine and the ethical review capacity in Africa"*
- Adebajo O. Adejumo, Chair, Department of Psychology, University of Ibadan, Ibadan, Nigeria, Member of National Health Research Ethics Committee of Nigeria (NHREC): *"The challenges and opportunities in establishing research ethics infrastructure in Nigeria"*
- h. 12.30 Discussion
- h. 13.00 Lunch
- h. 14.00 **II Session: Ethics, Human Rights and Health Protection**
- Chairpersons: Ersilia Grazia Spatafora, Godfrey B. Tangwa
- Charles Mgone, Executive Director, European and Developing Countries Clinical Trials Partnership – EDCTP: *"Capacity strengthening of the health research ethics review mechanism in sub-Saharan Africa through the EDCTP programme"*
- Jan Helge Solbakk, Chair of Medical Ethics and Head of Section, Section for Medical Ethics, Faculty of Medicine, University of Oslo, Norway: *"Goodness and ethics in biomedical research conducted in developing countries"* (Provisional title)
- Valeria Piccone, Judge, Human Rights Expert, Ministry of Justice, Italy: *"Human Rights and health in European Courts and legislation"*
- Jerome A. Singh, Head of Ethics and Health Law at the Centre for the AIDS Programme of Research in South Africa (CAPRISA), Honorary Research Fellow at the Howard College School of Law, University of KwaZulu-Natal, Durban, South Africa, and Adjunct Professor at the Faculty of Medicine, University of Toronto, Toronto, Canada: *"How human rights, health law, and the judiciary can enhance protection of human participants in biomedical research: lessons from South Africa"*
- h. 15.00 Discussion
- h. 15.30 **Focus on Africa: National and Regional Initiatives on Ethics in Biomedical Research**
- Chairpersons: Wenceslaus L. Kilama, Marie Charlotte Bouesséau
- Godfrey B. Tangwa, Associate Professor of Philosophy and Head of Department at the University of Yaoundé, Cameroon *"Ethical review of research in Cameroon"*
- Aissatou Toure, National Ethics Committee of Senegal, Institute Pasteur, Dakar, Senegal: *"The experience of Senegal in conducting ethical research"*
- Aceme Nyika, Ethics Coordinator, African Malaria Network Trust (AMANET): *"AMANET needs assessment survey of ethical review committees in Africa: overview of findings"*

- h. 16.15 Discussion
- h. 16.30 Coffee Break
- h.16.45 **III Session: The National Organizations in Support of Ethical Review of Biomedical Research**
- Chairpersons: Eva Bagenholm, Aissatou Toure
- Melody Lin, Deputy Director and Director of International Activities Program, Office for Human Research Protection, Department of Health and Human Services, United States of America: "*OHRP activities in building international ethical review capacity*"
- Umberto Filibeck, Director, GCP Promotion Unit, GCP and Pharmacovigilance Inspectorate, Italian Medicines Agency: "*The Italian legislation and the work of the Italian Medicine Agency in the field of ethics of clinical trials*"
- h. 17.15 Discussion

**Tuesday, 16 December**

- h. 9.00 **IV Session: Status of Health Research and Ethical Review Capacity in Developing Settings**
- Chairpersons: Henk ten Have, Jerome A. Singh
- Edlyn Jimenez-Santos, Research Fellow, Global Forum on Bioethics in Research, Council on Health Research and Development COHRED, "*Health research priorities in developing countries*"
- Juntra Karbwang, Clinical coordinator, UNICEF, UNDP, World Bank, WHO Special Programme for Research and Training in Tropical Diseases (TDR): "*The Strategic Initiative for Developing Capacity in Ethical Review 'SIDCER: The Asia experience*"
- Volnei Garrafa, Chairman, Post-Graduate Programme in Bioethics, University of Brasilia, Brazil: "*Helsinki 2008: a Latin American critical view*"
- Abdul Ghaffar, Research Policy and Cooperation, WHO Regional Office for the Eastern Mediterranean: "*Policy and practice challenges for research ethics in the Muslim world*"
- h.10.00 Discussion
- h.10.30 Coffee Break
- h.10.45 **V Session: The Process of Regulation of Medicines**
- Chairpersons: Antonio Bandini, Kristiina Kangaspunta
- Cav. Claudio Cavazza, Vice-President Farmindustria: "*Presentation on behalf of Farmindustria*"
- Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency: "*Clinical trials in developing countries submitted to EMEA for regulatory purposes*"
- Melba Gomes, Scientist, Evidence for Antimalarial Policy and Access, UNICEF, UNDP, World Bank, WHO Special Programme for Research and Training in Tropical Diseases (TDR): "*Ethical issues in a clinical trial of artesunate for malaria treatment*"

Roma Chilengi, Clinical Coordinator, AMANET: "*Challenges of ethical and regulatory review for malaria vaccine trials in Africa*"

Liliana Chocarro, Quality, Safety and Standard, Department of Immunization, Vaccines and Biologicals, WHO Geneva "*Status of regulatory oversight of clinical trials in Africa*"

h. 12.00 Discussion

h. 12.30 Conclusion and Recommendations

Kristiina Kangaspunta, Executive Officer, Applied Research Programme, UNICRI

Minister Antonio Bandini, Representative of the Italian Ministry of Foreign Affairs, Deputy Director of Directorate General for Sub Saharan Africa.